



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 516, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2021-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and a conditionally approved new animal drug application (cNADA) during July, August, and September 2021. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The incorporation by reference of other material listed in this rule was approved by the Director of the Federal Register as of November 25, 2011.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2021, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA's publication, "Approved Animal Drug Products Online (Green Book)" at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During July, August, and September 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 7, 2021	200-703	Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211	Carprofen Tablets	Dogs	Original approval as a generic copy of NADA 141-053	FOI Summary
July 15, 2021	141-545	VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524	TANOVEA (rabacfosadine for injection) Powder for Injection	Dogs	Full approval of conditionally approved cNADA 141-475 for the treatment of lymphoma	FOI Summary
August 2, 2021	200-708	Felix Pharmaceuticals PVT Ltd., 25-288 North Wall Quay, Dublin, 1, Ireland	Enrofloxacin Antibacterial Injectable Solution 2.27%	Dogs	Original approval as a generic copy of NADA 140-913	FOI Summary
August 16, 2021	200-618	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161	ZOLETIL (tiletamine and zolazepam for Injection)	Dogs and cats	Original approval as a generic copy of NADA 106-111	FOI Summary
August 18, 2021	200-709	Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India	Amoxicillin and Clavulanate Potassium for Oral Suspension	Dogs and cats	Original approval as a generic copy of NADA 055-101	FOI Summary
August 19, 2021	141-063	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	NUFLOR-S (florfenicol) Injectable Solution	Swine	Supplemental approval for the treatment of swine respiratory disease	FOI Summary

II. Withdrawal of Approval

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 093-329 for use of a sustained-release bolus containing sulfamethazine in cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this action. Elsewhere in this issue of the *Federal Register*, FDA gave notice that approval of NADA 093-329, and all supplements and amendments thereto, is withdrawn.

III. Change of Sponsor

VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524, has informed FDA that it has transferred ownership of, and all rights and interest in, newly approved NADA 141-545 for TANOVEA (rabacfosadine) for Injection to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140. The codification of this application in new 21 CFR 522.2065 will reflect this change of sponsorship.

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 500.1410 is amended to add uncooked edible tissues of swine to the standard for residues of *n*-methyl-2-pyrrolidone.
- 21 CFR 510.600 is amended to have sponsor addresses conform to the current style.
- 21 CFR 520.905c is amended to reflect the current label indications for use of fenbendazole paste in horses.
- 21 CFR 520.1044c is amended to reflect a current swine pathogen name for gentamicin soluble powder.
- 21 CFR 520.1660d is amended to revise conditions of use of oxytetracycline in drinking water of swine to reflect approved applications.
- 21 CFR 520.1780 is amended to revise the indications for use of pimobendan tablets in dogs.

- 21 CFR 520.2130 is amended to remove the 90-milligram strength for spinosad chewable tablets.
- 21 CFR 520.2220a is amended to add human food safety warnings for use of sulfadimethoxine concentrate solution and soluble powder.
- 21 CFR 520.2260b is amended to reflect the voluntary withdrawal of approval of an application for sustained-release boluses containing sulfamethazine and to correct the spelling of a disease condition.
- 21 CFR 520.2604 is amended to revise indications for use of tablets in dogs containing trimeprazine with prednisolone.
- 21 CFR 522.558 is amended to reflect the drug labeler code for the current sponsor of a dexmedetomidine injectable solution.
- 21 CFR 522.840 is amended to reflect the current classes of cattle approved for use of estradiol ear implants.
- 21 CFR 522.842 for testosterone propionate and estradiol benzoate implants is renamed to list the drug with the higher concentration first and redesignated to be listed in alphabetical order.
- 21 CFR 522.955 is amended to reflect the current scientific name of a bovine pathogen and the withdrawal periods for different formulations of florfenicol injectable solution.
- 21 CFR 522.1156 is amended to add subcutaneous administration to the approved conditions of use of imidocarb dipropionate solution in dogs.
- 21 CFR 522.2477 is amended to reorganize an approved use of trenbolone acetate and estradiol implants in steers.
- 21 CFR 524.770 is amended to reflect current label dosage information and human food safety warnings.
- 21 CFR § 529.1030 is redesignated as § 529.1004 in conformity with an announced FDA numbering system (40 FR 13802, March 27, 1975).

- 21 CFR 529.1940 is amended to add limitations to the use of progesterone intravaginal inserts in cows.
- 21 CFR 558.59 is amended to reference apramycin's status as a veterinary feed directive (VFD) drug and to add current limitations on VFD refills for apramycin medicated feeds.
- 21 CFR 558.205 is amended to reflect a current egg food safety warning for broiler chickens and growing turkeys fed Type C medicated feeds containing diclazuril.
- 21 CFR 558.254 is amended to remove an erroneous table title.
- 21 CFR 558.261 is amended to correct the upper inclusion rate for florfenicol in Type C medicated feed for freshwater-reared salmonids.
- 21 CFR 558.311 is being amended to codify free-choice Type C medicated cattle feeds containing lasalocid.
- 21 CFR 558.450 is amended to add conditions of use in honey bees for a Type C extender patty containing oxytetracycline.
- 21 CFR 558.633 is amended to add manufacturing limitations for use of Type C medicated swine feeds containing tylvalosin.
- 21 CFR 558.635 is amended to reflect a current egg food safety warning for broiler chickens fed Type C medicated feeds containing virginiamycin and diclazuril.

V. Incorporation by Reference

FDA is incorporating by reference an analytical method approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To obtain a copy of the analytical method, go to: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. You may inspect a copy at the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday.

This standard adds a method of detection for total for residues of the carcinogenic excipient *n*-methyl-2-pyrrolidone in uncooked edible swine tissues to a section established for a

method for residues of *n*-methyl-2-pyrrolidone in uncooked edible cattle tissues.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires *Federal Register* publication of “notice[s]... effective as a regulation,” of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Incorporation by reference, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 500, 510, 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 500--GENERAL

1. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

2. Revise § 500.1410 to read as follows:

§ 500.1410 N-methyl-2-pyrrolidone.

(a) *Standard for residues.* No residues of *n*-methyl-2-pyrrolidone may be found in the uncooked edible tissues of cattle and swine as determined by methods in paragraph (b) of this section.

(b) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday. It may be obtained from the sources indicated elsewhere in paragraph (b) of this section and at: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

(1) Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 240-402-7002.

(i) “Method of Analysis: *N*-methyl-2-pyrrolidone,” September 26, 2011; the method of analysis for uncooked edible tissues of cattle.

(ii) [Reserved]

(2) Merck Animal Health, 29160 Intervet Lane, Millsboro, DE 19966, 1-800-211-3573.

(i) “Determinative and Confirmatory Procedures for the Analysis of *N*-Methyl-2-pyrrolidone (NMP) in Swine Liver Tissue using LC-MS/MS,” July 20, 2017; the method of analysis for uncooked edible tissues of swine.

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 522.814 and 522.955 of this chapter.

PART 510--NEW ANIMAL DRUGS

3. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

4. In § 510.600:

a. In the table in paragraph (c)(1), revise the entries for “Anzac Animal Health, LLC”, “AquaBounty Technologies, Inc.”, “Dechra Veterinary Products LLC”, “Halocarbon Products Corp.”, “Kindred Biosciences, Inc.”, “Mizner Bioscience LLC”, “QBiotics Group Ltd.”, “Revivicor, Inc.”, and “Ridley USA, Inc.”, remove “Suite” and in its place add “suite”; and

b. In the table in paragraph (c)(2), revise the entries for “012164”, “017033”, “067949”, “086039”, “086053”, “086073”, “086078”, “086132”, and “086134”.

The revisions read as follows:

(c)* * *

(1) Alphabetical Listing of Sponsors

Firm name and address	Drug labeler code
* * * * *	
Anivive Lifesciences, Inc., 3250 Airflite Way, suite 400, Long Beach, CA 90807	086121

Anzac Animal Health, LLC, 218 Millwell Dr., suite B, Maryland Heights, MO 63043	086073
AquaBounty Technologies, Inc., 2 Mill and Main Pl., suite 395, Maynard, MA 01754	086053
* * * * *	
Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211	017033
* * * * *	
Halocarbon Products Corp., 6525 The Corners Pkwy., suite 200, Peachtree Corners, GA 30092	012164
* * * * *	
Kindred Biosciences, Inc., 1555 Bayshore Hwy., suite 200, Burlingame, CA 94010	086078
* * * * *	
Mizner Bioscience LLC, 225 NE Mizner Blvd., suite 760, Boca Raton, FL 33432	086039
* * * * *	
QBiotech Group Ltd., suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia	086132
* * * * *	
Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., suite 2400, Blacksburg, VA 24060	086134
Ridley USA, Inc., 111 W Cherry St., suite 500, Mankato, MN 56001	067949
* * * * *	

(2) Numerical Listing of Sponsors

Drug labeler code	Firm name and address
* * * * *	
012164	Halocarbon Products Corp., 6525 The Corners Pkwy., suite 200, Peachtree Corners, GA 30092
* * * * *	
017033	Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211
* * * * *	
067949	Ridley USA, Inc., 111 W Cherry St., suite 500, Mankato, MN 56001
* * * * *	
086039	Mizner Bioscience LLC, 225 NE Mizner Blvd., suite 760, Boca Raton, FL 33432
* * * * *	
086053	AquaBounty Technologies, Inc., 2 Mill and Main Pl., suite 395, Maynard, MA 01754
* * * * *	
086073	Anzac Animal Health, LLC, 218 Millwell Dr., suite B, Maryland Heights, MO 63043
086078	Kindred Biosciences, Inc., 1555 Bayshore Hwy., suite 200, Burlingame, CA 94010
* * * * *	
086121	Anivive Lifesciences, Inc., 3250 Airflite Way, suite 400, Long Beach, CA 90807
086132	QBiotech Group Ltd., suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia
086134	Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., suite 2400, Blacksburg, VA 24060
* * * * *	

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

5. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc, 360ccc-2, 371.

§ 516.2065 [Removed]

6. Remove § 516.2065.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

7. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

8. Revise § 520.88h to read as follows:

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When constituted, each milliliter (mL) of suspension contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin and clavulanate potassium equivalent to 12.5 mg clavulanic acid.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use--(1) Dogs--(i) Amount.* 6.25 mg/lb (1 mL/10 lb of body weight) twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli*. Treatment of periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats--(i) Amount.* 62.5 mg (1 mL) twice daily. Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5 to 7 days or 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: beta-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli*, *Pasteurella multocida*, and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

9. In § 520.905c, revise paragraphs (e)(1)(i) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(e) * * *

(1) * * *

(i) *Indications for use and amounts.* (A) For the treatment and control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*). For large strongyles, small strongyles, and pinworms, the recommended dose is 5 mg/kg (2.3 mg/lb).

(B) For treatment and control of ascarids (*Parascaris equorum*). For ascarids, the recommended dose is 10 mg/kg (4.6 mg/lb).

(C) For treatment and control of hypobiotic (encysted early third-stage), late third-stage, and fourth-stage cyathostome larvae, as well as fourth-stage *Strongylus vulgaris* larvae, the recommended dose is 10 mg/kg (4.6 mg/lb) daily for 5 consecutive days.

(D) For the control of arteritis caused by fourth-stage larvae of *Strongylus vulgaris* in horses.

(E) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in [paragraph \(e\)\(1\)\(i\)\(A\)](#) of this section and for treating infections of stomach bots as provided in [§ 520.2520](#).

* * * * *

10. In § 520.1044c, revise paragraph (d)(2) to read as follows:

§ 520.1044c Gentamicin sulfate powder.

* * * * *

(d) * * *

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Brachyspira hyodysenteriae*.

* * * * *

11. In § 520.1660d, revise paragraphs (d)(1)(iii)(A) and (C) to read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) *Amount.* Administer 10 milligrams per pound of body weight daily in drinking water. Administer up to 14 days; do not use for more than 14 consecutive days those products sponsored by Nos. 054771, 061133, and 069254. Administer up to 5 days; do not use for more than 5 consecutive days those products sponsored by Nos. 016592 and 061133.

* * * * *

(C) *Limitations.* Withdraw zero days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

12. In § 520.1780, revise paragraph (c)(2) to read as follows:

§ 520.1780 Pimobendan.

* * * * *

(c) * * *

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (e.g., furosemide, etc.) as appropriate on a case-by-case basis.

* * * * *

13. In § 520.2130, revise paragraph (a) to read as follows:

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

* * * * *

14. In § 520.2220a, revise paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to turkeys over 24 weeks (168 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 520.2260b [Amended]

15. In § 520.2260b, remove and reserve paragraphs (b) and (e); and in paragraph (f)(2)(ii) remove “diphtheria” and in its place add “diphtheria”.

16. In § 520.2604, revise paragraph (c)(2) to read as follows:

§ 520.2604 Trimeprazine with prednisolone tablets.

* * * * *

(c) * * *

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular, and nonspecific origins. As adjunctive therapy in various cough conditions including treatment of “kennel cough” or tracheobronchitis, bronchitis including allergic bronchitis, infections, and coughs of nonspecific origin.

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

17. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.558 [Amended]

18. In § 522.558, in paragraph (b)(1), remove “026637” and in its place add “017033”.

19. In § 522.812, revise paragraph (b)(1) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 016729, 017033, 055529, 058198, and 086101 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and

* * * * *

§ 522.840 [Amended]

20. In § 522.840, in paragraph (d)(2), in the first sentence, remove “confined steers and heifers” and in its place add “steers and heifers fed in confinement for slaughter”.

§ 522.842 [Redesignated as § 522.2343]

21. Redesignate § 522.842 as § 522.2343.

22. In § 522.955:

- a. Revise paragraph (b)(2);
- b. Redesignate paragraph (b)(3) as paragraph (b)(4) and add new paragraph (b)(3);
- c. In paragraphs (d)(1)(ii)(A)(2) and (d)(1)(ii)(B)(2), remove “*Haemophilus somnus*” and in its place add “*Histophilus somni*”;
- d. Revise paragraph (d)(1)(ii)(C); and
- e. Add paragraph (d)(2).

The revisions and additions read as follows:

§ 522.955 Florfenicol.

* * * * *

(b) * * *

(2) No. 000061 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(3) No. 086050 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. No. 000061: Animals intended for human

consumption must not be slaughtered within 38 days of subcutaneous treatment. No. 055529: Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Swine--(i) 300 mg/mL florfenicol in the inactive vehicles n-methyl-2- pyrrolidone, propylene glycol, and polyethylene glycol:

(A) *Amount.* 15 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(B) *Indications for use.* For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella Choleraesuis*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Glaesserella (Haemophilus) parasuis* in swine except for nursing piglets and swine of reproductive age intended for breeding.

(C) *Limitations.* Swine intended for human consumption must not be slaughtered within 11 days of the last intramuscular treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) [Reserved]

23. In § 522.1156, revise paragraph (c)(1) to read as follows:

§ 522.1156 Imidocarb solution.

* * * * *

(c) * * *

(1) *Amount.* Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular or subcutaneous injection. Repeat the dose after 2 weeks for a total of two treatments.

* * * * *

24. Add § 522.2065 to read as follows:

§ 522.2065 Rabacfosadine.

(a) *Specifications.* Each vial of powder contains 16.4 milligrams (mg) rabacfosadine. Each milliliter of constituted solution contains 8.2 mg rabacfosadine.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs--(1) Amount.* Administer rabacfosadine at 1 mg/kilogram body weight as a 30-minute intravenous infusion, once every 3 weeks, for up to 5 doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

25. Revise the section heading of newly designated § 522.2343 to read as follows:

§ 522.2343 Testosterone propionate and estradiol benzoate.

26. In § 522.2470, revise paragraph (b) introductory text to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) *Sponsors.* See Nos. 026637, 051311, and 054771 in § 510.600(c) of this chapter.

* * * * *

27. In § 522.2477, revise paragraph (b)(2), remove paragraph (d)(1)(i)(G), and add paragraph (d)(6) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), (d)(3)(iii), (d)(4), (d)(5), and (d)(6) of this section.

* * * * *

(d) * * *

(6) *Steers fed in confinement for slaughter*--(i) *Amount*. Each extended-release implant contains 200 mg trenbolone acetate and 40 mg estradiol (one implant consisting of 6 coated and 4 uncoated pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol).

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(iii) *Limitations*. Administer implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Effectiveness and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (steers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

28. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

29. In § 524.770, revise paragraphs (e)(1) and (e)(3) to read as follows:

§ 524.770 Doramectin.

* * * * *

(e) * * *

(1) *Amount*. Administer topically 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight.

* * * * *

(3) *Limitations*. Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

30. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1030 [Redesignated as § 529.1004]

31. Redesignate § 529.1030 as § 529.1004.

32. In § 529.1940, revise paragraph (e)(1)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(e) * * *

(1) * * *

(iii) *Limitations*. Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in anestrous lactating dairy cows less than 42 days or greater than 78 days postpartum. Do not use in lactating dairy cows less than 40 days postpartum. Do not use in beef cows that are less than 20 days postpartum. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use.

Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility.

Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, as provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

33. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

34. In § 556.710, revise paragraph (c) to read as follows:

§ 556.710 Testosterone.

* * * * *

(c) *Related conditions of use.* See § 522.2343 of this chapter.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

35. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

36. In § 558.59, redesignate paragraph (d) as paragraph (e) and add new paragraph (d) to read as follows:

§ 558.59 Apramycin.

* * * * *

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for apramycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for apramycin shall not be refilled.

* * * * *

37. In § 558.205, revise paragraphs (d)(1) and (2) to read as follows:

§ 558.205 Diclazuril.

* * * * *

(d) * * *

(1) *Chickens.* For chickens it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91		Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> ,	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption.	058198

		and <i>E. maxima</i> . Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> .		
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency. Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> .	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91	Bambermycins, 1 to 2	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency. Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> .	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	058198

(2) *Turkeys*. For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91		Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria</i>	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption.	058198

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
		<i>adenoeides</i> , <i>E. gallopavonis</i> , and <i>E. meleagrititis</i> .		
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria</i> <i>adenoeides</i> , <i>E. gallopavonis</i> , and <i>E. meleagrititis</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91	Bambermycins 1 to 2	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria</i> <i>adenoeides</i> , <i>E. gallopavonis</i> , and <i>E. meleagrititis</i> , and for improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198
(iv) 0.91	Bambermycins 2	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria</i> <i>adenoeides</i> , <i>E. gallopavonis</i> , and <i>E. meleagrititis</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

§ 558.254 [Amended]

38. In § 558.254, in paragraph (e) introductory text, remove “Table 2 - Size Proxies for SRCs in 2016”.

39. In § 558.261, revise paragraph (e)(2)(ii) to read as follows:

§ 558.261 Florfenicol.

* * * * *

(e) * * *

(2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
* * * * *		
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with <i>Flavobacterium</i> <i>psychrophilum</i> and furunculosis associated with <i>Aeromonas</i> <i>salmonicida</i>	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
* * * * *		

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39. In § 558.311, add paragraph (e)(3)(ix) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(3) * * *

Lasalocid amount	Indications for use	Limitations	Sponsor
* * * * *			
(ix) 60 to 300 mg of lasalocid per head per day	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) and replacement beef and dairy heifers on pasture: For increased rate of weight gain.	Feed continuously as a Type C free-choice medicated feed at a rate of 60 to 300 mg of lasalocid per head per day. Daily intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	054771

* * * * *

40. In § 558.450, revise paragraph (e)(5)(ii), redesignate paragraphs (e)(5)(iii) through (vii) as paragraphs (e)(5)(iv) through (viii), and add new paragraph (e)(5)(iii) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(5) * * *

Oxytetracycline amount	Indications for use	Limitations	Sponsor
* * * * *			
(ii) 200 mg/colony as a dust (200 mg/oz) or syrup (200 mg/5 lb)	Honey bees: For control of American foulbrood caused by <i>Paenibacillus larvae</i> and European foulbrood caused by <i>Melissococcus plutonius</i> susceptible to oxytetracycline	Apply every 4 to 5 days for a total of three applications. Remove at least 6 weeks prior to main honey flow.	066104 069254

(iii) 800 mg/colony as an extender patty (800 mg/patty).	Honey bees: For control of American foulbrood caused by <i>Paenibacillus larvae</i> and European foulbrood caused by <i>Melissococcus plutonius</i> susceptible to oxytetracycline	Use as a single application. Remove at least 6 weeks prior to main honey flow.	066104 069254
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41. In § 558.633, revise paragraph (d)(3) to read as follows:

§ 558.633 Tylvalosin.

* * * * *

(d) * * *

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form. Pelleted Type C medicated feeds must bear an expiration date of 30 days after the date of manufacture. Crumbled Type C medicated feeds must bear an expiration date of 7 days after the date of manufacture.

* * * * *

42. In § 558.635, revise paragraph (e)(1)(iv) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(1) * * *

Virginiamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
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(iv) 20	Diclazuril, 0.91	Broiler chickens: For prevention of necrotic enteritis caused by <i>Clostridium perfringens</i> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> . Because	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Diclazuril as provided by	058198
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		diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with <i>E. maxima</i> .	No. 058198 in § 510.600(c) of this chapter.	
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Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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